UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, MASSACHUSETTS CHAPTER OF AMERICAN ACADEMY OF PEDIATRICS, INC., AMERICAN CANCER SOCIETY, INC., AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, INC., AMERICAN HEART ASSOCIATION, INC., AMERICAN LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, TRUTH INITIATIVE FOUNDATION D/B/A TRUTH INITIATIVE, DR. TED KREMER, DR. JONATHAN WINICKOFF and DR. LYNDA YOUNG, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION Defendant.	Civil Action No. 16-cv-11985 (IT)

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules for Civil Procedure and Local Rule 56.1, Defendant United States Food and Drug Administration ("FDA") hereby moves for summary judgment against all plaintiffs.

In this case, FDA timely issued a statutorily mandated rule requiring large graphic health warnings for cigarettes in 2011, but that rule was vacated on First Amendment grounds and remanded back to the agency when the D.C. Circuit found (among other critiques) that "the strength of [FDA's] evidence is underwhelming." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1220 (D.C. Cir. 2012), *reh'g & reh'g en banc denied*, Nos. 11-5332 & 12-5063 (D.C. Cir. Dec. 5, 2012), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 26 (D.C. Cir. 2014). On remand, FDA developed a new rulemaking plan, and has been conducting

research to create a robust record supporting new warnings. It is currently converting new image concepts for the rule into final images, and simultaneously seeking Office of Management and Budget (OMB) review to begin quantitative research on proposed text warning components for the rule.

Plaintiffs contend that FDA has "unlawfully withheld or unreasonably delayed" issuing a new rule, contrary to the Administrative Procedure Act (APA), 5 U.S.C. § 706(1). Courts considering such claims, including the First Circuit, generally apply, first and foremost, a "rule of reason," and five other factors (one of which is the presence of any statutory deadlines). *Telecommc'ns Research & Action Ctr. v. FCC* ("*TRAC*"), 750 F.2d 70, 80 (D.C. Cir. 1984). Applying the "rule of reason," it is entirely appropriate for FDA to continue executing its current, carefully considered, plan to complete its new rulemaking, informed by the D.C. Circuit's critiques in the *Reynolds* vacatur decision.

Plaintiffs instead ask this Court to apply two different decisions – one from a judge in this District and one from the Tenth Circuit – that have not been followed in binding precedents from any other jurisdiction. Doing so would effectively require the Court to hold, counterfactually, that FDA never issued any rulemaking at all, or at minimum, that a statutory deadline for an initial rulemaking applies with full force to a new rulemaking after a remand and vacatur. It would further require the Court to hold that an agency's failure to meet such a renewed statutory deadline is a *per se* violation of the APA, curtailing the agency's ability to apply its expertise in preparing a new rule, supported by strong evidence.

In support of this motion, FDA is filing a Memorandum of Points and Authorities and a Local Rule 56.1 Statement of Undisputed Material Facts (in turn supported by the Declaration of Mitchell Zeller, Director of FDA's Center for Tobacco Products).

Per the Court's scheduling order (ECF No. 26), FDA has consolidated its memorandum in support of this Cross Motion for Summary Judgment with its Opposition to plaintiffs' Motion for Summary Judgment.

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs requested oral argument. FDA does not oppose that request.

LOCAL RULE 7.1(a)(2) CERTIFICATE

Counsel for FDA hereby certify pursuant to Local Rule 7.1(a)(2) that they have conferred in good faith with counsel for plaintiffs in an effort to resolve or narrow the issues raised by this motion.

Respectfully submitted,

Dated: May 26, 2017

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as nonregistered participants on today's date.

/s/ Daniel K. Crane-Hirsch
May 26, 2017